

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND)	
COMPOUNDING PHARMACY, INC.)	MDL No. 2419
PRODUCTS LIABILITY LITIGATION)	Dkt. No. 1:13-md-2419-FDS
_____)	
)	
This Document Relates to:)	
)	
Barger, et al. v. Ameridose, LLC et al.)	Dkt. No. 1:13-cv-12619-FDS

MEMORANDUM OF LAW IN SUPPORT OF
MOTION FOR SUMMARY JUDGMENT OF
SAINT THOMAS OUTPATIENT NEUROSURGICAL CENTER, LLC,
HOWELL ALLEN CLINIC, A Professional Corporation, JOHN CULCLASURE, M.D.,
and DEBRA SCHAMBERG, R.N.

The Defendants, Saint Thomas Outpatient Neurosurgical Center, LLC ("STOPNC"), Howell Allen Clinic, a Professional Corporation ("Howell Allen"), John Culclasure, M.D. ("Dr. Culclasure"), and Debra Schamberg, R.N. ("Ms. Schamberg") (collectively "Defendants"), have respectfully moved for summary judgment pursuant to Rule 56 of the Federal Rules of Civil Procedure.

In support of the Motion, the Defendants have contemporaneously filed:

1. Statement of Undisputed Material Facts.
2. Affidavit of John Culclasure, M.D.

In addition, the Defendants file this Memorandum of Law in Support of their Motion for Summary Judgment.

Statement of the Case

The Plaintiffs' health care liability action arises from the fungal meningitis outbreak caused by contaminated, preservative-free, methylprednisolone acetate ("MPA") manufactured and sold by New England Compounding Pharmacy, Inc., d/b/a New England Compounding Center ("NECC").

The Plaintiffs received epidural steroid injections of MPA manufactured by NECC and sold to STOPNC.¹ Dr. Culclasure and other physicians at STOPNC performed the Plaintiffs' injections.² The Plaintiffs received the injections as part of medical treatment for pain.³ The Plaintiffs claim that they were injured because contaminated NECC medication was injected during these medical procedures.⁴ All claims for injuries in the Complaint relate to the provision of these health care services to the Plaintiffs.

The Plaintiffs assert the following causes of action against STOPNC and Howell Allen, and against the individual health care providers, Dr. Culclasure and Ms. Schamberg:

- Claims pursuant the Tennessee Products Liability Act of 1978⁵
- Common law claims for civil conspiracy⁶
- Common law claims for breach of a duty to prevent a foreseeable harm⁷
- Claims for breach of express and implied warranties pursuant Tenn. Code Ann. §§ 47-2-313, 47-2-314, and 47-2-315.⁸

¹ Complaint at ¶¶ 6, 7, and 191; Affidavit of John W. Culclasure, M.D., ¶¶ 3, 8 (attached hereto as Exhibit A).

² Ex. A ¶¶ 3, 8.

³ Ex. A ¶¶ 3, 4, and 8.

⁴ Complaint at ¶ 7.

⁵ Complaint at ¶¶ 230-54.

⁶ Complaint at Count I.

⁷ Complaint at Count II.

⁸ Complaint at ¶¶ 188-201; 230-54.

The Complaint seeks to hold Howell Allen liable for the actions of STOPNC and the individual Defendants, and to hold it strictly liable on the product liability claim.⁹

Summary of Argument

As explained below, the Plaintiffs' Complaint falls squarely within Tennessee's expansive statutory definition of a "health care liability action," defined as "any civil action, including claims against the state or a political subdivision thereof, alleging that a health care provider or providers¹⁰ have caused an injury related to the provision of, or failure to provide, health care services¹¹ to a person, regardless of the theory of liability on which the action is based."¹²

The Plaintiffs allege that the Defendant health care providers caused injury to the Plaintiffs related to the provision of health care. Thus, under the statutory definition, this is a "health care liability action." Because this is a "health care liability action," the Complaint may proceed *only* as a "health care liability action" governed by the Tennessee Health Care Liability Act (the "Act"). All other causes of action, irrespective of the labels chosen to describe the claims, are precluded by the Act. The Plaintiffs must also satisfy statutory pre-suit, and certificate of good faith requirements of the Act.¹³

⁹ Complaint at ¶ 195, 254.

¹⁰ "Health care provider" is defined to explicitly include physicians, nurses, and health care facilities such as STOPNC and Howell Allen. Tenn. Code Ann. § 29-26-101.

¹¹ The statute defines "health care services" as "care by health care providers, which includes care by physicians, nurses, licensed practical nurses, pharmacists, pharmacy interns or pharmacy technicians under the supervision of a pharmacist, orderlies, certified nursing assistants, advance practice nurses, physician assistants, nursing technicians and other agents, employees and representatives of the provider, and also includes staffing, custodial or basic care, positioning, hydration and similar patient services." Tenn. Code Ann. § 29-26-101.

¹² Tenn. Code Ann. § 29-26-101.

¹³ Tenn. Code Ann. § 29-26-101 ("Any such civil action or claim is subject to this part regardless of any other claims, causes of action, or theories of liability alleged in the complaint").

The instant Plaintiffs have attempted to bring causes of action outside the Health Care Liability Act, inconsistent with the plain language of the Act. Because the sole allowable remedy when a Tennessee plaintiff claims injury related to the provision of health care services is pursuant the Health Care Liability Act, *all* causes of action *not* brought pursuant the Act must be dismissed.

Regardless, even if the Plaintiffs have properly asserted a health care liability action, the Plaintiffs have failed to comply with the statutory requirements for filing a “health care liability action.” Specifically, the Plaintiffs failed to comply with the pre-suit notice requirements of Tenn. Code Ann. § 29-26-121, and failed to attach a certificate of good faith to their Complaint, an indispensable requirement of Tenn. Code Ann. § 29-26-122.

The Plaintiffs’ failure to comply with the certificate of good faith requirement of Tenn. Code Ann. § 29-26-122 mandates dismissal of Plaintiffs’ claims *with prejudice*. In addition, and in the alternative, Plaintiffs’ failure to comply with the pre-suit notice requirements of Tenn. Code Ann. § 29-26-121 mandates dismissal of Plaintiffs’ claims.

Standard of Review

When considering a Fed. R. Civ. P. 56 motion for summary judgment, the Court “shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law. The court should state on the record the reasons for granting or denying the motion.”¹⁴

¹⁴ Fed. R. Civ. P. 56.

The question before the Court is whether the Plaintiffs can sustain the claims stated in their Complaint against Defendants considering the undisputed material facts.

As explained below, the Complaint is clearly a “health care liability action” as defined by the statute. As a “health care liability action,” the Plaintiffs may only bring a cause of action pursuant the Act and must follow the explicit requirements of the Act. The Plaintiffs here, however, attempt to assert causes of action outside the Act, and simultaneously fail to meet the requirements of the Act to bring a health care liability action.

Thus:

1. The claims of the Complaint not permitted under the Act as “health care liability actions” (e.g., civil conspiracy, product liability, breach of a duty to warn, breach of warranty) should be dismissed.
2. The claims of the Complaint pled properly as “health care liability” actions should be dismissed for non-compliance with the pre-suit notice and certificate of good faith requirements of the statute.

The Defendants are entitled to summary judgment on all claims of the Complaint.

Law and Argument

I. Introduction

In Tennessee, a plaintiff has one cause of action against a health care provider when the plaintiff’s claim “relates” to the “provision of” “health care services.”¹⁵ That single available cause of action is a “health care liability action” governed by the Tennessee Health Care Liability Act, codified at Tenn. Code Ann. § 29-26-101, *et seq.*

¹⁵ Tenn. Code Ann. § 29-26-101(a).

Put simply, because the Complaint against the Defendants arises from the Defendants' provision of health care services, the substantive law of the forum state requires the Plaintiffs to bring their Complaint as a "health care liability action" pursuant the Health Care Liability Act. The Health Care Liability Act explicitly precludes any cause of action not brought pursuant the Act when the claimed injuries relate to the provision of health care. The Plaintiffs simply cannot bring a health care liability action and attempt to re-label the substantive basis for liability as claims for product liability, civil conspiracy, breach of a duty to prevent a foreseeable harm, or breach of warranty.

Any claim of the Complaint not brought pursuant the Act, i.e., the claims for product liability, civil conspiracy, breach of a duty to warn, and breach of warranty, must be dismissed, as the exclusive remedy in this case is pursuant the Act.

Second, when bringing a health care liability action, which this Complaint clearly is, the Plaintiffs must comply with the Act's pre-suit notice requirements and good faith certificate requirements. The Plaintiffs, however, seek to pursue this health care liability action without complying with the pre-suit notice and good faith certificate requirements. This – even assuming the Plaintiffs have properly pled a health care liability action – mandates dismissal of the action.

II. Plaintiffs' Causes of Action Not Asserted as Health Care Liability Actions pursuant the Health Care Liability Act Fail as a Matter of Law against Defendants.

As previewed above and explained below, the Plaintiffs' exclusive cause of action for injuries related to the provision of health care services in this case is a "health care liability action" brought pursuant the Act.

a) Plaintiffs' Claims Must Be Brought under the Health Care Liability Act.

1) The Health Care Liability Act Broadly Defines what Qualifies as a "Health Care Liability Action."

The Health Care Liability Act applies to any action in which a plaintiff alleges an injury arising from the provision of health care services:

"Health care liability action" means **any civil action**, including claims against the state or a political subdivision thereof, **alleging that a health care provider or providers have caused an injury related to the provision of, or failure to provide, health care services to a person, regardless of the theory of liability on which the action is based.**¹⁶

Prior to the adoption, in 2011, of the definitional section in § 29-26-101, the scope of what constituted a "medical malpractice" action was governed by the common law, which defined a "medical malpractice" action as any claim bearing "substantial relationship to the rendition of medical treatment by a medical professional, or concerning medical art, science, training, or expertise" ¹⁷

¹⁶ Tenn. Code Ann. § 29-26-101(a) (emphasis added) (applicable to any cause of action occurring on or after October 11, 2011).

¹⁷ See, e.g., *Estate of French v. Stratford House*, 333 S.W.3d 546 (Tenn. 2011); see also *Dunlap v. Laurel Manor Health Care*, No. E2012-02432-COA-R3-CV, 2013 WL 4680494, n. 1 (Tenn. Ct. App. August 29, 2013).

The Health Care Liability Act, passed in 2011, changed the name of a “medical malpractice” action to “health care liability action” and codified the definition of a “health care liability action.” The unambiguous definition broadly captures *any* civil action *against a health care provider* claiming that the health care provider *caused injury related to the provision of health care services*.¹⁸ The statutory language further illustrates the intent to capture, and govern, any and all health care-related claims by adding “regardless of the theory of liability on which the action is based.”¹⁹

The Tennessee Supreme Court has recognized that, when the history of an amendment to a definitional provision reflects the Tennessee General Assembly’s intent to broaden the meaning of the term, courts should interpret the term “as broadly as possible.”²⁰

Thus, here, the definition of a “health care liability action” – which is already broadly cast in the statutory language – must also be construed as broadly as possible given the General Assembly’s obvious intent to broaden the scope of what constitutes a (formerly called) medical malpractice action to be prosecuted only pursuant the Act.

The Health Care Liability Act broadly defines “health care services” as:

(b) Health care services to persons **includes care by health care providers, which includes care by physicians, nurses,** licensed practical nurses, **pharmacists,** pharmacy interns or pharmacy technicians under the supervision of a pharmacist, orderlies, certified nursing assistants, advance practice nurses, physician assistants, nursing technicians and other agents, employees and representatives of the provider, and also includes staffing, custodial or basic care, positioning, hydration and similar patient services.²¹

¹⁸ Tenn. Code Ann. § 29-26-101.

¹⁹ Tenn. Code Ann. § 29-26-101.

²⁰ *Lee Medical, Inc. v. Beecher*, 312 S.W.3d 515, 531 (Tenn. 2010) (noting the legislature’s amendments to broaden the Tennessee Peer Review Act).

²¹ Tenn. Code Ann. § 29-26-101(b) (emphasis added).

Like the definition of a “health care liability action,” the statutory definition of “health care services” in the Health Care Liability Act is intentionally broad and non-limiting.

It includes non-physician services performed by agents, employees, representatives, and other support staff. It also includes “basic” and “custodial” care, which, in Tennessee, was previously not considered to fall within the scope of a medical malpractice action.²² Expansion of the Act to govern cases involving “basic” or “custodial” care clearly illustrates the General Assembly’s intent to broaden the scope of what constitutes a health care liability action.

Reading the definition of “health care liability action” and the definition of “health care services” together, the General Assembly’s intent to broaden the number of cases that must be brought pursuant the Act is clear. The definition of “health care liability action” is broad, should be read broadly, and should be applied broadly.

2) The Plaintiffs’ Complaint Is a “Health Care Liability Action.”

When deciding what cause of action a Complaint asserts, courts look at the “gravamen” of the complaint.²³ Aside from that traditional rule, the Court must also analyze the Complaint guided by the definitional sections of the Health Care Liability Act outlined above.

First, the Defendants are clearly health care providers subject to the protection of the Health Care Liability Act. Dr. Culclasure is a licensed physician.²⁴ Debra Schamberg is a registered nurse.²⁵ STOPNC is a licensed ambulatory surgery center.²⁶

²² See *Estate of French v. Stratford House*, 333 S.W.3d 546, 557 (Tenn. 2011).

²³ *Estate of French*, 333 S.W.3d at 557.

²⁴ Ex. A, ¶ 15.

Second, the allegations of the Complaint clearly fall within the definition of a “health care liability action.”

Every act attributed to the Defendant health care providers in the Complaint was done in furtherance of the provision of health care services to the Plaintiffs. All allegedly wrongful acts described in the Complaint “relate to” the “provision of” “health care services.”

Most importantly, the Plaintiffs’ Complaint claims injuries that clearly relate to the provision of health care services, which triggers the Complaint falling within the statutory definition of a “health care liability action” as one claiming injuries “relating to” the “provision of” health care services²⁷:

7. The Plaintiffs’ injections of MPA caused them various injuries and medical conditions including, but not limited to, fungal meningitis, localized spinal or paraspinal infections (i.e. epidural abscesses, arachnoiditis, phlegmon, etc.), anxiety, depression, and complications associated with lumbar punctures. The Plaintiffs’ injections of MPA also caused them to undergo various unnecessary and painful medical treatments including, but not limited to, lumbar punctures, blood patches, hospitalizations, MRIs, and CT scans.²⁸

²⁵ Complaint at ¶ 36.

²⁶ Ex. A, ¶ 16.

²⁷ Tenn. Code Ann. § 29-26-101(a).

²⁸ Complaint at ¶ 7.

Even prior to adoption of the Health Care Liability Act in 2011, Tennessee courts have consistently recognized at common law that the selection and administration of a prescription medication is a health care service:

Prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect. **As a medical expert**, the prescribing physician can take into account the propensities of the drug as well as the susceptibilities of his patient. His is the task of weighing the benefits of any medication against its potential dangers. **The choice he makes is an informed one, and individualized medical** judgment bottomed on a knowledge of both patient and palliative.²⁹

Any claim arising from the selection and administration of prescribed medication is necessarily a claim that relates to the provision of health care services. As such, it is a “health care liability action” that *must* be brought pursuant the Health Care Liability Act.

Thus, the instant Plaintiffs must bring any and all claims pursuant the Act.

²⁹ *Dooley v. Everett*, 805 S.W.2d 380, 386 (Tenn. Ct. App. 1990) (quoting *Stone v. Smith, Kline & French Labs.*, 731 F.2d 1575 (11th Cir. 1984)) (recognizing the learned intermediary doctrine) (emphasis added); see also *Dunlap*, 2013 WL 4680494, at *6 (“[t]he proper administration of prescribed medicine is, in fact, medical treatment”).

- b) **The Health Care Liability Act Precludes Strict Liability Claims and Claims Premised on Causes of Action other than Health Care Liability for Injuries Arising from the Provision of Health Care Services.**
 - 1) **The General Assembly Made Clear that Any Action against a Health Care Provider for Injury Related to the Provision of Health Care Services May Only Be Brought pursuant the Health Care Liability Act.**

The Health Care Liability Act establishes the uniform, and exclusive, remedy for injuries arising from a health care provider's services.³⁰

Every cause of action arising from any injury "relating to" a health care provider's provision of health care services must be brought as a "health care liability action":

"Health care liability action" means **any** civil action, including claims against the state or a political subdivision thereof, **alleging that a health care provider or providers have caused an injury related to the provision of**, or failure to provide, health care services to a person, **regardless of the theory of liability** on which the action is based.³¹

The General Assembly made clear that the substantive and procedural requirements for "health care liability actions" apply to *all* claims relating to a health care provider's provision of health care services, regardless of how the plaintiff drafts a complaint, labels the claims, or styles the allegations:

Any such civil action or claim is subject to this part regardless of any other claims, causes of action, or theories of liability alleged in the complaint; provided, that no provision of this part shall apply to claims against the state to the extent that such provision is inconsistent with or conflicts with the Tennessee Claims Commission Act, compiled in title 9, chapter 8, part 3.³²

³⁰ See Tenn. Code Ann. § 29-26-101, *et seq.*

³¹ Tenn. Code Ann. § 29-26-101(a) (emphasis added) (applicable to any cause of action accruing on or after October 11, 2011).

³² Tenn. Code Ann. § 29-26-101(c) (emphasis added).

The Plaintiff cannot skirt the requirements of the Act by attempting to disguise a clear “health care liability action” as one for product liability, civil conspiracy, breach of a duty to warn, or breach of warranty, and attempting to alter the elements required to prove the claim or the burden of proof. This Complaint must be brought pursuant the Health Care Liability Act, and only pursuant the Act.

2) Other Common Law or Statutory Causes of Action Are Precluded by the Health Care Liability Act.

As explained above, these Plaintiffs must bring this Complaint as a “health care liability action.” The statute specifically states that a claim related to the provision of health care must be brought as a “health care liability action” “regardless of the theory of liability on which the action is based.”³³ It further states that the requirements of the Act apply to the Complaint regardless of any other claims, causes of action, or theories of liability in the Complaint.³⁴

Thus, because the Complaint alleges injuries related to the provision of health care services, the Plaintiffs must bring this Complaint as a “health care liability action” and are precluded from bringing causes of action other than “health care liability actions” against these Defendants for the claimed injuries.

The Missouri Supreme Court’s decision in *Budding v. SSM Healthcare System*³⁵ is instructive on the exclusion of causes of action other than health care liability against health care providers for wrongs committed related to the provision of health care services.

³³ Tenn. Code Ann. § 29-26-101(a).

³⁴ Tenn. Code Ann. § 29-26-101(c).

³⁵ 19 S.W.3d 678 (Mo. 2000).

In *Budding*, the plaintiff sued the defendant health care provider for strict products liability, alleging that a Vita teflon implant used by the defendant to rebuild the plaintiff's jaw was "defective."³⁶ The issue before the court was whether Missouri's health care liability act³⁷ precluded the plaintiff's products liability claim.³⁸

The court recognized that it had to interpret the Missouri health care liability act and acknowledged that its "role in interpreting these statutes is to 'ascertain the intent of the legislature from the language used, to give effect to that intent if possible, and to consider the words used in their plain and ordinary meaning.'"³⁹ Discharging this responsibility, the court found that the Missouri health care liability statute "eliminate[d] liability of health care providers for strict products liability."⁴⁰

The Missouri court reasoned:

The legislature has spoken with reasonable clarity expressing an intent to eliminate liability of health care providers for strict products liability. All canons of statutory construction are subordinate to the requirement that the Court ascertain and apply the statute in a manner consistent with that legislative intent.⁴¹

The court placed primary emphasis on the legislature's use of the term "any action" in defining the scope of the statute and held: "by using the words 'any action' in sec. 538.225.1, the legislature clearly demonstrated its intent that the statute not only apply to a negligence action but to a products liability action as well."⁴²

³⁶ *Id.* at 679.

³⁷ See "Tort Actions Based on Improper Health Care" § 538.205, RSMo 2013, *et seq.*

³⁸ *Budding*, 19 S.W.3d at 681.

³⁹ *Id.* at 680 (internal citation omitted).

⁴⁰ *Id.* at 681.

⁴¹ *Id.*

⁴² *Id.* at 680.

The Tennessee Health Care Liability Act uses similar language, defining a “health care liability action” as “any civil action” relating to an injury suffered from the provision of health care services.⁴³ The Tennessee statute *goes even further*, stating that the Health Care Liability Act applies to any claim “regardless of the theory of liability on which the action is based.”⁴⁴

As in *Budding*, the Tennessee General Assembly has “spoken with reasonable clarity” that any claim for injuries related to the provision of health care services must be brought as a “health care liability action” pursuant the Health Care Liability Act.

Claims for strict product liability against health care providers for injuries related to the provision of health care services are not permitted under Tennessee’s Health Care Liability Act.^{45 46} Liability, without fault, without proof of a departure from accepted

⁴³ Tenn. Code Ann. § 29-26-101(a).

⁴⁴ *Id.*

⁴⁵ Additionally, the Act specifically precludes any presumption of negligence against a health care provider in an action related to the provision of health care services. Tennessee Code Annotated § 29-26-115(c) states that, “[i]n a health care liability action as described in subsection (a), there shall be no presumption of negligence on the part of the defendant[.]” The General Assembly has thus clearly (1) stated that all actions against health care providers related to the provision of health care services must be brought pursuant the Act and (2) stated an intention that health care providers not be presumed negligent in actions brought for injury related to the provision of health care services.

⁴⁶ This is consistent with the overwhelming precedent followed in jurisdictions across the country which do not permit product liability claims against health care providers for injury related to the provision of health care services. See *Ayyash v. Henry Ford Health Systems*, 533 N.W.2d 353, 210 Mich. App. 142 (Ct. App. 1995); *Brandt v. Boston Scientific Corp.*, 792 N.E.2d 296 (Ill. 2003); *Budding v. SSM Healthcare System*, 19 S.W.3d 678 (Mo. 2000); *Cafazzo v. Cent. Medical Health Services*, 542 Pa. 526 (1995); *Cobb v. Dallas Fort Worth Medical Center-Grand Prairie*, 48 S.W.3d 820 (Tex. App. 2001); *Doyle v. Planned Parenthood of Seattle-King County, Inc.*, 31 Wn. App. 126 (Wash. App. 1982); *Easterly v. Hospital of Texas, Inc.*, 772 S.W.2d 211 (Tex. App. 1989); *Eby v. Milton S. Hershey Medical Center*, 31 Pa. D. & C.4th 121 (Pa. C.P. 1996); *Femrite v. Abbott Northwestern Hospital*, 568 N.W.2d 535 (Minn. App. 1997); *Ferguson v. EBI Medical Systems*, 1995 WL 462438 (Conn. Super. Aug. 1, 1995); *Foster v. Memorial Hospital Ass’n*, 219 S.E.2d 916 (W. Va. 1975); *Goldfarb v. Teitelbaum*, 149 A.D.2d 566 (N.Y. App. Div. 1989); *Greenberg v. Michael Reese Hospital*, 83 Ill.2d 282 (Ill. 1980); *Hector v. Cedars-Sinai Medical Center*, 180 Cal. App. 3d 493 (Cal. App. 1986); *Herrick v. Middlesex Hospital*, 2005 WL 1760785 (Conn. Super. June 27, 2005); *Hoff v. Zimmer*, 746 F. Supp. 872 (W.D. Wis. 1990); *Hollander v. Sandoz Pharmaceuticals Corp.*, 289 F.3d 1193 (10th Cir. 2002); *Hoven v. Kelble*, 79 Wis. 2d 444 (Wis. 1977); *Howell v. Spokane & Inland Empire Blood Bank*, 114 Wn. 2d 42 (Wash. 1990); *Iacangelo v. Georgetown University*, 2006 WL 4391359 (Mag. D.D.C. Oct. 11, 2006); *In re Breast Implant Product Liability*, 331 S.C. 540 (1998); *Johnson v. Mountainside Hospital*, 571 A.2d 318 (N.J. Super. App. Div. 1990); *Johnson v. Sears, Roebuck & Co.*, 355 F. Supp. 1065 (E.D. Wis. 1973); *Karibjanian v. Thomas Jefferson*

standards of professional practice, which proximately caused an injury which would not otherwise have occurred, is *not* a valid claim under the Health Care Liability Act.

Causes of action under other common law or statutory theories are precluded by the Health Care Liability Act as the Act governs *any* civil action alleging that a health care provider caused an injury related to the provision of health care services to a person, *regardless of the theory of liability* on which the action is based.⁴⁷

The Plaintiffs' claims against these Defendants asserting theories labeled as claims for product liability, civil conspiracy, breach of a duty to warn, and breach of warranty, are precluded by the Tennessee Health Care Liability Act because the Complaint alleges injuries related to the provision of health care services.

Claims brought as common law or statutory causes of action, not as "health care liability actions," must be dismissed.

University Hospital, 717 F. Supp. 1081 (E.D. Pa. 1989); *Lambert v. Charlotte Hungerford Hospital*, 2006 WL 3491275 (Conn. Super. Nov. 2, 2006); *LaValla v. Parker*, 1991 WL 17757 (E.D. Pa. Feb. 12, 1991); *Leith v. Henry Ford Hospital*, 2000 WL 33420641 (Mich. App. May 16, 2000); *McCombs v. Southern Regional Medical Center, Inc.*, 504 S.E.2d 747 (Ga. App. 1998); *McKenna v. Harrison Memorial Hospital*, 960 P.2d 486 (Wash. App. 1998); *NME Hospitals, Inc. v. Azzariti*, 573 So. 2d 173 (Fla. App. 1991); *North Miami General Hospital, Inc. v. Goldberg*, 520 So. 2d 650 (Fla. App. 1988); *Pantano v. Teletronics Pacing Systems, Inc.*, 1996 WL 107099 (W.D.N.Y. Feb. 15, 1996); *Parker v. St. Vincent Hospital*, 919 P.2d 1104 (N.M. App. 1996); *Perlmutter v. Beth David Hospital*, 308 N.Y. 100 (N.Y. 1954); *Pierson v. Sharp Memorial Hospital, Inc.*, 216 Cal. App. 3d 340 (Cal. App. 1989); *Pleasant v. Dow Corning Corp.*, 1993 WL 1156110 (D.S.C. Jan. 7, 1993); *Podrat v. Codman-Shurtleff, Inc.*, 384 Pa. Superior Ct. 404 (Pa. Super. 1989); *Probst v. Albert Einstein Medical Center*, 440 N.Y.S.2d 2 (N.Y. App. Div. 1981); *Roberts v. Suburban Hospital*, 532 A.2d 1081 (Md. App. 1987); *Roell v. Stryker Corp.*, 2007 WL 2783357 (S.D. Miss. Sept. 21, 2007); *Royer v. Catholic Medical Center*, 144 N.H. 330 (N.H. 1999); *Samuels v. Health & Hospital Corp.*, 432 F. Supp. 1283 (S.D.N.Y. 1977); *San Diego Hospital Ass'n. v. Superior Court*, 30 Cal. App. 4th 8, (Cal. App. 1994); *Satorius v. Proassurance Wisconsin Insurance Co.*, ___ N.W.2d ___, 2012 WL 5319213 (Wis. App. Oct. 30, 2012); *Shepard v. Alexian Brothers Hospital*, 33 Cal. App. 3d 606 (Cal. App. 1973); *Shivers v. Good Shepherd Hospital, Inc.*, 427 S.W.2d 104 (Tex. Civ. App. 1968); *Silverhart v. Mount Zion Hospital*, 20 Cal. App. 3d 1022 (Cal. App. 1971); *Simone v. Long Island Jewish Hillside Medical Center*, 81 Misc. 2d 163 (N.Y. Sup. 1975); *Snyder v. Mekhjian*, 244 N.J. Super. 281 (N.J. Super. App. Div. 1990); *St. Mary Medical Center, Inc. v. Casko*, 639 N.E.2d 312 (Ind. App. 1994); *Tucker v. Kaleida Health*, 2011 WL 1260117 (W.D.N.Y. March 31, 2011); *Vergott v. Deseret Pharmaceutical Co.*, 463 F.2d 12 (5th Cir. 1972); *Von Downum v. Synthes*, 2012 WL 5463900 (N.D. Okla. Nov. 8, 2012); *Weissman v. Dow Corning Corp.*, 892 F. Supp. 510 (S.D.N.Y. 1995); *Zbras v. St. Vincent's Medical Center*, 880 A.2d 999, 1002 (Conn. App. 2005); *Zelle v. Bayer Corp.*, 2012 WL 1435192 (Conn. Super. Feb. 2, 2012).

⁴⁷ Tenn. Code Ann. § 29-26-101(a) (emphasis added) (applicable to any cause of action accruing on or after October 11, 2011).

III. The Plaintiffs' "Health Care Liability Action" Should Be Dismissed with Prejudice for Failure to Comply with Tenn. Code Ann. § 29-26-122 and Dismissed for Failure to Comply with Tenn. Code Ann. § 29-26-121.

Since Plaintiffs' Complaint is a health care liability action governed by the Health Care Liability Act, the Complaint must comply with the pre-suit notice and certificate of good faith requirements of the Health Care Liability Act. Complaints that fail to comply with the pre-suit and certificate of good faith requirements of the section should be dismissed.

a) The Plaintiffs Did Not Comply with Tenn. Code Ann. § 29-26-122.

Tenn. Code Ann. § 29-26-122(a) requires that claimants file a certificate of good faith *with the complaint* for any "health care liability action in which expert testimony is required."

The certificate of good faith must reflect that the claimant has consulted with a qualified expert, who provided a written statement certifying that there is a good faith basis for each element of health care liability under Tenn. Code Ann. § 26-29-115, based on the expert's review of the claimant's medical records and other available materials.⁴⁸

"The filing of a certificate of good faith indicating that an expert has reviewed the claims and has certified that they are taken in good faith 'satisfies the goal of attempting to ensure that suits proceeding through litigation have some merit.'"⁴⁹

⁴⁸ Tenn. Code Ann. § 29-26-122(a).

⁴⁹ *Caldwell v. Vanderbilt Univ.*, No. M2012-00328-COA-R3-CV, 2013 WL 655239, *5 (Tenn. Ct. App. 2013) (additional citations omitted).

T.C.A. 29-26-122 mandates dismissal for failure to file a certificate of good faith with the complaint:

(a) In any health care liability action in which expert testimony is required by § 29-26-115, the plaintiff or plaintiff's counsel **shall** file a certificate of good faith with the complaint. **If the certificate is not filed with the complaint, the complaint shall be dismissed, as provided in subsection (c), absent a showing that the failure was due to the failure of the provider to timely provide copies of the claimant's records requested as provided in § 29-26-121 or demonstrated extraordinary cause.**

...

(c) The failure of a plaintiff to file a certificate of good faith in compliance with this section shall, upon motion, **make the action subject to dismissal with prejudice.**⁵⁰

The Plaintiffs did not file a certificate of good faith with the Complaint, despite this being a “health care liability action” and despite the explicit requirement of the statute. The Complaint must be dismissed with prejudice.⁵¹

b) The Plaintiffs Did Not Comply with Tenn. Code Ann. § 29-26-121.

Tenn. Code Ann. § 29-26-121(a) mandates that a claimant “shall” give written notice of a health care liability action to a potential defendant “at least sixty (60) days before filing a complaint based upon health care liability in any court of this state.” This pre-suit notice must include information about the patient, claimant, plaintiff’s attorney, other potential defendants, and include a HIPAA compliant authorization.⁵²

⁵⁰ Tenn. Code Ann. § 29-26-121 (emphasis added).

⁵¹ See, e.g., *Myers v. AMISUB (SFH), Inc.*, 382 S.W.3d 300, 312 (Tenn. 2012) (“[W]e are dismissing Mr. Myers’s complaint with prejudice as the result of his failure to comply with Tennessee Code Annotated section 29-26-122. . . .”); see additionally *Caldwell*, 2013 WL 655239, at *6-7 (affirming dismissal for failure to file compliant certificate of good faith); *Jackson v. HCA Health Services of Tennessee, Inc.*, 383 S.W.3d 497, 498-99 (Tenn. Ct. App. 2012) (affirming dismissal of complaint for failure to file certificate of good faith and affirming constitutionality of good faith certificate requirement).

⁵² Tenn. Code Ann. § 29-26-121(a).

The pre-suit notice requirement is intended to allow health care providers to investigate and resolve claims before a lawsuit is filed.⁵³ When a plaintiff files a cause of action subject to the Health Care Liability Act, Tenn. Code Ann. § 29-26-121 mandates that the complaint “shall state whether each party has complied with subsection [§ 29-26-121](a) and shall provide the documentation specified in subdivision (a)(2).”⁵⁴

“[T]he court has discretion to excuse compliance with this section *only for extraordinary cause shown*.”⁵⁵ Failure to comply with Tenn. Code Ann. § 29-26-121 results in dismissal.⁵⁶

The Plaintiffs did not comply with the pre-suit notice requirements of § 29-26-121.⁵⁷ Additionally, the Plaintiffs have not asserted or demonstrated “extraordinary cause” excusing their non-compliance.

The Plaintiffs’ claims should be dismissed because of this failure to comply with the mandatory notice requirements.

⁵³ See *Williams v. SMZ Specialists, PC*, No. W2012-00740-COAR9-CV, 2013 WL 1701843, *8-9 (Tenn. Ct. App. 2013) (explaining policy reasons behind pre-suit notice requirement).

⁵⁴ Tenn. Code Ann. § 29-26-121(b).

⁵⁵ Tenn. Code Ann. § 29-26-121(b).

⁵⁶ See, e.g., *Childs v. UT Medical Group*, 398 S.W.3d 163, 172 (Tenn. Ct. App. 2012) (affirming dismissal where notice non-compliant and certificate of good faith non-compliant); *DePue v. Schroeder*, No. E2010-00504-COA-R9, 2011 WL 5388645, *1 (Tenn. Ct. App. 2011) (mandating dismissal where plaintiff waited 53 days, not 60 days, after sending notice); *Stevens v. Hickman Cmty. Health Care Servs., Inc.*, No. M2012-00582-SC-S09-CV (Tenn. 2013) (affirming dismissal where plaintiff did not substantially comply with notice requirements).

⁵⁷ Complaint at ¶ 255.

CONCLUSION

In 2011, the Tennessee General Assembly established the comprehensive Health Care Liability Act, which recast medical malpractice actions as “health care liability actions” and codified a very broad definition of “health care liability action.” Under the plain statutory language, any lawsuit alleging that a health care provider caused an injury related to the provision of health care services, *regardless of the theory of liability*, is a “health care liability action” subject to the requirements of Tennessee Code Annotated § 29-26-101, *et seq.*

The Plaintiffs’ Complaint against the Defendant health care providers asserts injuries related to the provision of health care services. The exclusive cause of action is a “health care liability action,” and any causes of action, other than those permitted by the Act, are precluded as a matter of law.

Aside from the substantive limitations on permissible claims, the Act imposes mandatory pre-suit and certificate of merit requirements.

The Plaintiffs suit is a “health care liability action,” despite the failure to comply with the requirements of the Health Care Liability Act, and despite the effort to disguise their action as claims for strict product liability, civil conspiracy, breach of a duty to warn, and statutory breach of warranty. This is not allowed by the clear statutory language of the Act and the obvious legislative intent.

The Plaintiffs’ claims for causes of action not stated as “health care liability actions” should be dismissed. The Plaintiffs’ claims for “health care liability” should also be dismissed for failure to comply with the pre-suit notice and certificate of good faith requirements.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that this document filed through the CM/ECF system will be served electronically to the registered participants identified on the Notice of Electronic Filing and copies will be e-mailed or mailed via regular U.S. mail to those participants identified as unregistered this 9th day of December, 2013.

/s/ Chris Tardio

Chris Tardio